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FDA Regulation of OTC Drug Products Hearing
26 June 2000

Good morning. I'm Tara Shochet from the American Society for Emergency Contraception. I'm here to tell you why emergency contraceptives should be sold over the counter. (Sometimes called morning after pills, emergency contraceptives are really just ordinary birth control pills that women can take soon after unprotected sex to prevent pregnancy.) They're best known for the treatment of rape victims, but any woman suffering a contraceptive accident might benefit from taking them if she acts quickly. Emergency contraceptives hold the potential to cut unwanted pregnancies and abortions in America by 50% and to save up to a billion dollars each year in health care costs. Emergency contraception is the clearest example of a misclassified prescription drug in America today.

You already know that emergency contraceptive pills were deemed safe and effective by the FDA in a published statement in 1997. More recently, in the past two years, the FDA approved two brands of specially packaged pills to be marketed for emergency use: Preven in 1998 and Plan B in 1999. The World Health Organization considers both of these to be Essential Drugs and declares them to have no contraindications.[1] In addition, it is now clear that emergency contraceptives work better the sooner they are taken. The WHO published a study last year in the *Lancet* showing dramatic improvements in effectiveness when women were able to start the therapy within 12 hours of unprotected sex rather than waiting until the traditional limit of 72 hours. Indeed, the risk of pregnancy is eight times as high when treatment is started close to the 72 hour mark, as compared to when it is started in the first 12 hours after unprotected sex. Every hour lost tracking down a doctor and waiting for a prescription boosts a woman's risk of unwanted pregnancy.

Now, a prescription requirement might be justified, even if it slows down the woman's efforts to start treatment. But it would be justified only if it served an important purpose. The American Society for Emergency Contraception has examined the evidence and sees no significant purpose at all. For the rest of my testimony today, I'll review the reasons people might think prescription status

[1] The only listed contraindication is established pregnancy. This is only because no form of contraception can prevent a pregnancy if a woman is already pregnant. The pills will not interrupt or harm an existing pregnancy.

generally helps to safeguard women. Then I'll explain why we think each does not hold in the case of emergency contraception. First I'll cover medical reasons, then I'll turn to social reasons. Finally, I will mention what is happening in Europe and in some special cases here in the States where emergency contraceptives are sold directly in pharmacies.

What are the medical reasons to keep a pill on prescription status? Do women need help diagnosing their need for emergency contraception? Not at all. If women didn't think they needed the therapy, they'd never make a doctor's appointment for a prescription in the first place. The doctor does not need to do a physical exam, and as with aspirin or decongestant, there's little harm done if a woman takes the pills when she doesn't actually need them. According to the World Health Organization, there are no women on earth who should absolutely avoid the drug. All women take the same dose and same brands, so they don't need help there. Is the therapy difficult to administer? No. It's just a few simple pills. Are the pills addictive, and would an overdose be dangerous? No, and no. We need to remember that oral contraceptives (and by extension emergency contraceptives) are among the safest and best-studied drugs in the history of medicine.

Could there be compelling social reasons to limit emergency contraceptives to prescription status? Perhaps it's not the job of the FDA to consider this in the first place, but let's examine the evidence anyway. Some opponents of women's reproductive rights might allege that women will abuse emergency contraceptives if they are available without the clinician as gatekeeper. It's not clear how this abuse could occur, unless women microwaved the pills perhaps or backed over them with a pickup truck. But if people are worried that women who have easier access to ECs will throw away their more effective regular contraceptives and rush out to have unprotected sex just for the chance to use emergency contraceptives, they can rest easy. Women will use emergency contraceptives as responsibly as they do any other medication. Looking to Washington State, where women have been able to get emergency contraceptives directly from the pharmacies since 1998, there is no evidence of any abuse. And in a study recently published in the *New England Journal*, researchers in Scotland told what happened when they actually gave women emergency contraceptives ahead of time to keep on hand in case of need. These women did not substitute the emergency contraceptives for their regular methods, and the pregnancy rate was lower than that in a control group. Indeed, based on this and other evidence, the British Medicines Control Agency is currently re-classifying emergency contraceptives so that they will be available directly from the pharmacies. British pharmacists and the British Medical Association support this move, as does the Royal College of Obstetricians and Gynecologists. In France, emergency contraceptives are available today directly from pharmacists without a doctor's prescription.

It's time American women had the same access to emergency contraception as European women do! These pills are safe, simple and effective, and they work best when they are started without delay. When responsible adults get a medically unnecessary run around while they are trying to prevent unwanted pregnancy after a contraceptive accident, something is wrong. Requiring prescription for using emergency contraception is as foolish as requiring prescriptions for using fire extinguishers. Thank you.

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